

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

v.

AMERICAN HOME PRODUCTS  
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8426

Bartle, C.J.

March 11, 2010

Eldeane Sheffer ("Ms. Sheffer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Bert D. Sheffer, Ms. Sheffer's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated June 17, 2002, Dr. Johnson attested in Part II of Ms. Sheffer's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of

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3. (...continued)  
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

50% to 60%.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix B-1,<sup>5</sup> Level II benefits in the amount of \$41,589.<sup>6</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, David A. Rawling, M.D., F.A.C.C., stated that Ms. Sheffer had "[m]oderate mitral regurgitation," which he measured as 23%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In July, 2005, the Trust forwarded the claim for review by Karen K. Hamilton, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Hamilton concluded that there was no reasonable medical basis for Dr. Johnson's finding that

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4. Dr. Johnson also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. In her Green Form, claimant requested benefits on Matrix A-1. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not contest, that Ms. Sheffer was eligible only to receive benefits on Matrix B-1 because claimant's pharmacy records reflected Diet Drug usage of 60 days or less. See Settlement Agreement § IV.B.2.d.(2)(b).

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Hamilton explained that:

The left atrium is quite large in this patient (33 cm<sup>2</sup> traced by the sonographer and 29 cm<sup>2</sup> traced by me). As a percent of the [left atrial] area the [mitral regurgitant] jets are only mild (14-16% of the [left atrial] area). No [mitral regurgitant] jets were traced by the sonographer.

In the Report of Auditing Cardiologist Opinions Concerning Green From Questions At Issue, Dr. Hamilton also stated that she "traced 3 of the largest contiguous [mitral regurgitant] jets I could find; the [mitral regurgitant/left atrial] jet area ratios ranged from 14-16%."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Sheffer's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that the auditing cardiologist's determinations are inconsistent with the findings on her echocardiogram report. Dr.

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Sheffer's claim.

Rawling, a cardiologist who participated in the Trust's Screening Program, performed the echocardiogram on Ms. Sheffer and prepared the "Echo Report," which was used by claimant in her Gray Form to obtain Fund A Benefits.<sup>8</sup> In addition, claimant argued that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."<sup>9</sup> Claimant further noted that there is only "a slight difference of opinion" between the auditing cardiologist and the attesting physician and that a "4% to 6% difference of opinion" as to claimant's mitral regurgitation should not result in the denial of her claim for Matrix Benefits. Finally, claimant contended that the Trust was not properly applying the "reasonable medical basis" standard established in the Settlement Agreement as the auditing cardiologist simply substituted her opinion for that of the attesting physician.<sup>10</sup>

The Trust then issued a final post-audit determination again denying Ms. Sheffer's claim. Claimant disputed this final determination and requested that the claim proceed to the show

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8. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement). Under the Settlement Agreement, the Gray Form is used to report on the results from the Screening Program. See Settlement Agreement §§ VI.C.2.f & VI.C.4.a.(8).

9. In support of this assertion, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, addressed claimant's echocardiogram.

10. Ms. Sheffer also submitted a report for an October 15, 2004 echocardiogram, which she argues confirms Dr. Johnson's representation that she had moderate mitral regurgitation.

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Sheffer's claim should be paid. On January 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006, and claimant submitted a sur-reply on June 23, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Sheffer reasserts the arguments that she made in contest. Claimant further avers that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of mitral regurgitation and, as such, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust counters that claimant failed to establish a reasonable medical basis for her claim because claimant did not rebut any of Dr. Hamilton's specific findings.

In her sur-reply, claimant reasserts that "echocardiogram interpretation is highly subjective." Claimant also maintains that the Trust failed to acknowledge that Dr. Johnson was merely concurring with Dr. Rawling's original diagnosis that claimant had moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Hamilton's finding that Ms. Sheffer had only mild mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Sheffer rests only on Dr. Johnson's check-the-box diagnoses on her Green Form and Dr. Rawling's echocardiogram report. Ms. Sheffer does not refute or respond to Dr. Hamilton's determination that claimant's

echocardiogram did not establish moderate mitral regurgitation due to the improper measurement of claimant's left atrium and that, upon proper measurement, claimant's mitral regurgitation was only mild.<sup>11</sup> Mere disagreement with the auditing cardiologist, however, is insufficient to meet claimant's burden of proof.<sup>12</sup> On this basis alone, claimant has failed to meet her burden in proving that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames;

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11. Claimant also asserted, without any medical support, that "[c]laimant's left atrial enlargement, to which there is no dispute, supports the diagnosis of 'moderate' mitral regurgitation." As claimant provided no support or explanation as to how the mere existence of an abnormal left atrial dimension establishes that she has the requisite level of mitral regurgitation, the court does not accept this assertion by claimant.

12. We also reject claimant's assertion that there is a reasonable medical basis for her claim because two cardiologists concluded that she had moderate mitral regurgitation. A claimant cannot establish a reasonable medical basis for his or her claim simply by accumulating cardiologist opinions or echocardiogram reports.



(2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Hamilton determined in audit, and Ms. Sheffer does not dispute, that the attesting physician's finding of moderate mitral regurgitation was based on an incorrect measurement of claimant's left atrium, which resulted in an erroneous diagnosis of moderate mitral regurgitation. Similarly, Dr. Hamilton determined that, after proper measurement, claimant's mitral regurgitation was only mild. Such an unacceptable practice by claimant's attesting physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.<sup>13</sup>

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13. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Hamilton merely substituted her opinion for that of the attesting physician. Instead, Dr. Hamilton specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation based on clearly identified deficiencies in the attesting physician's conclusion. Neither claimant nor

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We also disagree with claimant's argument that there must be a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitant because "a 4% to 6% difference" is only "a slight difference of opinion" between the auditing cardiologist and the attesting physician. The Settlement Agreement establishes specific criteria to establish moderate mitral regurgitation. Nothing in the Settlement Agreement allows a claimant to recover Matrix Benefits where the claimant relies on a measurement close to that required by the Settlement Agreement. To conclude otherwise would allow claimants who do not have moderate mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement. See generally PTO No. 2640 at 8 n.5 ("A claimant with mitral regurgitation at 19.9% RJA/LAA, a level just below moderate, is ineligible for benefits.").

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim for Matrix Benefits was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. Claimant's reliance on the echocardiogram obtained as a result of the Screening Program is misplaced. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive

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13. (...continued)  
claimant's attesting physician, however, chose to refute or respond to this determination.

for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Settlement Agreement § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. See, e.g., PTO No. 2662 at 13 ("[W]e find that good cause exists under the Settlement Agreement to modify the Trust's procedures to order it to designate all Fund B claims for audit."). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an

immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Sheffer's claim for Matrix Benefits and the related derivative claim submitted by her spouse.